

July 3, 2000

Page 3

46. (Twice Amended) An isolated and purified fragment of the *P. haemolytica* genome, wherein said fragment modulates the expression of TbpA, said fragment consisting of a nucleotide sequence from about 10 to 200 bases in length which is 5' to the open reading frame depicted in SEQ ID NO: 1 or a degenerate variant of said open reading frame.

17. (Amended) [An organism] A host cell which has been altered to contain the polynucleotide of claim 30.

### REMARKS

Claims 30-51 are currently pending in the subject application. Claims 42 and 48 stand withdrawn from examination. Claims 34, 35, and 47 stand objected to on the grounds that they introduce new matter into the application. Claims 30-41, 43-47 and 49-51 stand rejected under 35 U.S.C. § 112, paragraph 2. Claims 30, 31, 33, 36-39, 43, 44, 46, 47 and 49-51 stand rejected under 35 U.S.C. § 102 and/or 103. By deduction, claims 32, 34, 35, 40, 41, and 45 are free of the art of record. Applicants submit that, upon entry of the present amendments, these objections and rejections will be overcome.

### The Amendments

The Sequence Listing enclosed herewith is submitted to correct an error in the originally filed Sequence Listing which would be readily apparent to the skilled person. Due to a clerical error, eight (8) nucleotides were omitted from SEQ ID NO:1, between nucleotide 2144 and nucleotide 2145. Because of this omission, SEQ ID NO:1 as filed did not encode SEQ ID NO:2, but rather SEQ ID NO:1 contained a termination codon that would result in a 717 amino acid truncated polypeptide. The skilled person would recognize the need to insert nucleotides corresponding to the missing codons for the amino acids listed in SEQ ID NO:2. Furthermore, the nucleic acid sequence encoding SEQ ID NO:2 is provided in the application as originally filed in Figure 21 (the condons missing from the original Sequence Listing appear on line 36), and SEQ ID NO:1 as shown in the Sequence Listing enclosed herewith contains nucleotides corresponding to the missing codons. Thus, no new matter is added to the application by

replacement of the erroneous sequence in the original Sequence Listing with the correct sequence from Figure 21.

Claims 30, 43, 44 and 46 are amended herein to recite that the claimed nucleic acids are "isolated and purified" as defined in the specification on page 8, lines 30-32. Claim 1 is also amended to clarify that "stringent conditions" as recited in the claim are the conditions described in the specification on page 9, lines 25-31. Finally, claim 47 is amended to clarify that the claim is drawn to a host cell (which may be part of an organism) which contains the nucleic acid sequence of this invention. Such host cells are disclosed in the specification, *inter alia*, on page 4, lines 12-15, 21-23, and 26-28; page 10, lines 30-32; page 13, lines 9-16; and page 18, lines 16-20.

These amendments are fully supported in the application as-filed, for example on the pages mentioned above. Applicants submit that the amendments put the claims in condition for allowance or in better condition for appeal in accordance with 37, C.F.R. 1.116. Therefore, Applicants respectfully request that the amendments be entered in the application.

#### **Objection Under 35 U.S.C. § 132**

Claims 34, 35, and 47 stand objected to based on the Examiner's assertion that these claims include new matter. This objection is respectfully traversed.

Claims 34 and 35 recite portions of SEQ ID NO:1 which include nucleotide 2790, which is the first nucleotide of the stop codon at the 3' end of the coding sequence. Due to the error discussed above, the originally filed Sequence Listing indicated that the 3' terminal nucleotide of SEQ ID NO:1 was number 2784, but the correct number for the 3' terminal nucleotide of SEQ ID NO:1 is 2792 (the last nucleotide of the stop codon). Thus, the portions recited in claims 34 and 35 fall within the sequence of SEQ ID NO:1 as shown in the Sequence Listing submitted herewith, and these claims do not introduce new matter into the application.

Claim 47 is amended herein to change the recitation in the claim from "An organism ..." to "A host cell ..." which language is specifically recited in the specification, as indicated in the above discussion of the amendments. Applicants respectfully request that the objection to claims 34, 35 and 47 under 35 U.S.C. § 132 be withdrawn.

**Rejection Under 35 U.S.C. §112, second paragraph**

Claims 30-41, 43-47, and 49-51 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that, subsequent to entry of the present amendments, the claims are clear and unambiguous.

Claim 30 is amended herein to specifically recite the wash conditions for stringent hybridization as set out in the specification on page 9. Thus, claim 30 as amended provides a clear standard for ascertaining the metes and bounds of the claimed nucleic acids. Applicants respectfully submit that claims 30-40, 43-44, 46-47 and 49-51, as amended herein, particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

**Rejection Under 35 U.S.C. §102(b)**

Claims 30-31, 33, 43-44, and 46-47 stand rejected under 35 U.S.C. §102(b) as anticipated by Murphy, et al. (1993). This rejection is respectfully traversed.

Applicants respectfully point out that the pending claims, as amended herein, are drawn to isolated and purified nucleic acid, which is defined in the specification on page 8, lines 30-32 as, "free of sequences which naturally flank the nucleic acid [ ] from which the nucleic acid is derived." Murphy discloses a preparation of total genomic DNA from a particular organism, and the DNA fragments disclosed by Murphy will inherently contain the flanking sequences found in the organism whose total DNA is prepared. This is not isolated and purified nucleic acid as defined in the specification, page 8, lines 30-32, and therefore Murphy, et al. (1993) does not disclose or suggest the nucleic acid claimed herein.

Furthermore, Murphy provides no guidance on separating fragments of DNA which will hybridized under stringent conditions with the sequences recited in the Sequence Listing from other fragments of genomic DNA. Thus, Murphy does not enable the public to obtain the nucleic acid of amended claim 30 or claims dependent thereon. Chester v. Miller, 906 F.2d 1574, 1577 n.2, 15 USPQ2d 1333, 1336 n.2 (Fed. Cir. 1990) ("To be prior art under section

E

102(b) the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure.").

Applicants respectfully request that the rejection of claims 30-31, 33, 43-44, and 46-47 under 35 U.S.C. §102(b) be withdrawn.

**Rejection Under 35 U.S.C. §103(a)**

Claims 30-31, 33, 36-39, 43-44, 46-47, and 49-51 stand rejected under 35 U.S.C. §103(a) as unpatentable over Murphy, et al., described above, in view of Schryvers, et al., (1992) and further in view of Loosmore, et al. Applicants note that amended claim 30 does recite "stringent hybridization conditions" and, as set forth above, Murphy does not provide an isolated nucleic acid as claimed. Nor does Murphy provide any guidance by which the skilled worker might reasonable expect to obtain the claimed nucleic acid fragments from the total genomic DNA provided by Murphy. Therefore, the claims as amended herein are not obvious over Murphy.

Furthermore, the Schryvers, et al. and Loosmore, et al. references do not supply the deficiencies of Murphy. In particular, neither Schryvers nor Loosmore provide any reasonable expectation of success in isolating and/or purifying the claimed nucleic acid. Therefore, claims 30-31, 33, 36-39, 43-44, 46-47, and 49-51 are not obvious over cited references for the reasons provided herein and in the previous response. Applicants respectfully request that the rejection of the claims as amended herein under 35 U.S.C. §103(a) be withdrawn.

Applicants note that claims 32, 34, 35 and 40 have not been rejected under 35 U.S.C. §§102 or 103, and therefore have been indicated to be free of the prior art.

*July 3, 2000*

*Page 7*

**Conclusion**

Applicants respectfully submit that all of the pending claims, as amended herein, are now in condition for allowance, and respectfully request an indication of same. If the Examiner believes that prosecution may be furthered by discussing the application, in person or by telephone, with Applicants' representatives, we would welcome the opportunity to do so.

Respectfully submitted,

BAKER BOTTS L.L.P.

Dated: July 3, 2000  
Baker Botts L.L.P.  
The Warner; Suite 1300  
1299 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2400  
(202) 639-7700 (telephone)  
(202) 639-7890 (facsimile)  
LHP/nej

By:

  
Laurence H. Posorske  
Registration No. 34,698